K063505

DEC 1 2 2006

510(k) Summary

In accordance with the Safe Medical Devices Act of 1990 and in compliance with 21CFR 807, the following serves as the 510(k) Summary information upon which the substantial equivalence determination is based.

Contact Information

Submitter:	BioTex, Inc. 8058 El Rio St. Houston, TX 77054
Phone:	713.741.0111
Contact Person:	Matthew Fox
Date Prepared:	11/15/2006

Device Names

Trade/Proprietary Name:	Visualase ENVISION Software System
Common Name:	MRI Analysis Software
Classification:	Picture Archiving and Communications System
Product Code:	LLZ: Image Processing System
Reg.Class:	Class II
Reg. Number:	21CFR892.2050

Predicate Device

GE Medical Systems:	Advantage Windows Workstation with FuncTool option (K960265).

Description of Device

The Visualase ENVISION platform consists of a PC-based Linux workstation running the ENVISION software tools in an X-windows environment. The device uses a standard Ethernet connection to retrieve image data files from a compatible MRI scanner host. The images may be retrieved as soon as they have been stored on the MRI host, facilitating near real-time analysis of dynamic MRI data.

The Visualase ENVISION software tools perform three primary functions: 1) Image transport, 2) Image processing, and 3) Data display. The Image transport tools negotiate communication with the MRI scanner host, determine the availability of images, facilitate retrieval of image files, facilitate local storage of image files, and notify Image processing tools of new data. The Image processing tools extract relevant data from available MR images and update data analysis information. The Data display tools provide visualization and facilitate manipulation of the data extracted by the Image processing tools.

Data may be processed to display dynamic changes in voxel intensity as a function of image acquisition. Such analysis is useful in analyzing the uptake and washout of MR contrast agents and can be useful for discrimination of tissue type or state. When data from compatible sequences is available, images may also be processed to extract the complex phase angle of voxels as a function of image acquisition. Using proton-resonance-frequency (PRF) shift analysis and image subtraction, changes in complex phase angle may be related back to relative changes in temperature during the study.

The Visualase ENVISION software is compatible with General Electric Signa model MR scanners and can be configured to operate with either LX or EXCITE format images.

Indications for Use

The Visualase ENVISION workstation is intended to retrieve, store, process, and display temporally dynamic magnetic resonance (MR) data from compatible scanners. The software is capable of analyzing either temporal changes in image intensity as is useful in, for example, dynamic contrast enhancement studies, or temporal changes in complex phase of image data as is useful in, for example, in phase contrast angiography or in determinations of dynamic phase changes related to temperature changes in soft tissues. The image data may be manipulated and viewed in a number of different ways and the value of data at certain selected points may be monitored and/or displayed over time. When interpreted by a trained physician, this device provides information that may be useful in the determination or assessment of a diagnosis, intervention, or course of treatment. Patient management decisions should not be made solely on the basis of Visualase ENVISION analysis.

Comparison to Predicate Device

Attachment 4 of this submission contains substantial equivalence table of comparison. The tables compare the indications and technological features of the Visualase ENVISION Software System and the predicate device.

Addition of supplemental information to those images extracted from MR temporal datasets has previously been given 510(k) clearance in General Electric's Advantage Windows Workstation with FuncTool option (K960265). Similar to FuncTool, Visualase ENVISION software allows analysis of temporal MRI datasets, and displays data similar to the former's parametric images formulated from user supplied functions, image difference functions (including phase difference), and mapping of specified color ramps onto images.

Technical Performance

Computation:
The Visualase ENVISION software system uses 32-bit float or integer representations (as appropriate) to manipulate data. Raw, processed, and computed images are converted to lossless X-windows Pixmap (XPM) format for display and for transfer between applications. Data loss from repeated calculations is unlikely because all output images are re-computed directly from transferred data. For example, when image "contrast" is adjusted by the user, the resulting image is generated based on transformation of the original input data and not relative to the previous output data. Data loss from image representation is unlikely since input images have 16 bits-per-pixel depth and representations used for computation are 32-bits deep.

Artifacts:
The most likely source of artifacts from the ENVISION analysis software is the appearance of "phase breaks" in phase difference images due to imperfect phase unwrap during difference calculation. The likelihood of phase breaks occurring during phase difference images is minimized by using both real and imaginary MR images as inputs and by utilizing a full complex-phase-difference implementation for sequential image differencing (as is implemented in the ENVISION software). If phase breaks or unexpected changes in phase do occur, they are most likely due to 1) extremely long echo times (TE) during a gradient echo sequence, or 2) motion of the subject under study during the acquisition. Motion of the image subject may lead to other artifacts as well. As is always the case in MR imaging, techniques for minimizing motion during the scanning sequence should be observed.

Conclusion

BioTex has demonstrated the Visualase ENVISION Software System is substantially equivalent to the predicate device based on design, technical performance, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Matthew Fox
Engineering Manager
BioTex, Inc.
8058 El Rio St.
HOUSTON TX 77054

DEC 12 2006

Re: K063505
Trade/Device Name: Visualase ENVISION Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 15, 2006
Received: November 21, 2006

Dear Mr. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063505

Device Name:

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063505